Psychometric Evaluation of the Ostomy Complication Severity Index

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Abstract

Background: Almost one million individuals are estimated to be currently living with an ostomy in North America, and more than 120,000 new ostomies are created annually in the United States and Canada.[1-3] Although this surgery saves lives, up to 80% of patients experience ostomy complications.[4-7] To reduce these complications and their negative impact on patients' lives, we must expand our knowledge of both their incidence and severity. However, no available instruments have sufficient evidence of reliability and validity to measure ostomy complications. In addition, few studies have been conducted using a conceptual framework to examine ostomy complications.

Purpose: The purpose of this study was to evaluate the psychometric properties of a new instrument to measure incidence and severity of ostomy complications early in the postoperative period. We developed an evidence-based conceptual model to guide development and evaluation of this new instrument, the Pittman Ostomy Complication Severity Index (OCSI). This article will report on the development and psychometric testing of the OCSI.

Method: Psychometric testing of the OCSI was, conducted with a convenience sample of 71 participants from three acute care settings within a large healthcare system in the Midwestern United States. Descriptive analyses, content validity indices, inter-rater reliability testing, and construct validity testing were employed.

Results: Of the 71 participants, most were men (52%), white (96%), and married or partnered (55%), and the mean age was 57 years. Fifty-two (84%) participants experienced at least one ostomy complication in the 60-day post-operative period. Common complications included: leakage (60%), peristomal irritant dermatitis (50%), stomal pain (42%), retraction (39%), and

stomal bleeding (32%). The OCSI demonstrated acceptable evidence of content validity (CVI= 0.9) and inter-rater reliability for individual items (k= .71- 1.0), as well as almost perfect agreement for total scores among raters (ICC .991, $p \leq .001$). Construct validity of the OCSI was supported by significant correlations among variables in the conceptual model (complications, risk factors, stoma care self-efficacy, and ostomy adjustment).

Conclusion: The OCSI has evidence of reliability and validity, and it can be used to assess incidence and severity of ostomy complications in the early postoperative period. The OCSI is brief, easy to use, and clinically practical, and it can be used to a) identify priority areas for nursing intervention related to the ostomy, b) determine appropriate interventions to prevent or treat complications, and c) evaluate the effects of nursing interventions designed to improve outcomes for patients with ostomies.

Key Words: Ostomy complications, psychometric properties, instrument, risk factors, self-efficacy, ostomy adjustment

Introduction

Almost one million individuals are estimated to be currently living with an ostomy in North America, and more than 120,000 new ostomies are created annually in the United States and Canada.[1-3] Although this surgery saves lives, up to 80% of patients experience ostomy complications[4-7] that affect them both physically and psychologically. Physically, patients experience peristomal irritant dermatitis, stoma pain, stomal bleeding, stoma necrosis, mucocutaneous separation, herniation, infection, and stoma retraction.[4,6,8] Psychologically, adjustment to living with an ostomy can be difficult. Not only does the individual have to cope with a serious and often life-threatening diagnosis, but placement of an ostomy requires significant changes to his or her lifestyle. This population is at risk for psychological and social difficulties that affect long-term adjustment. People with ostomies face difficulties adjusting to and coping with their ostomy, social isolation, occupational changes, and challenges in daily living.[9-11]

Adjustment to living with an ostomy becomes more difficult in the presence of complications. Complications require complex ostomy management techniques and additional use of costly ostomy equipment and supplies, and they can disrupt daily, occupational, social, and physical activities. Improvements have occurred in the management of an ostomy, including advanced surgical techniques/procedures and innovative new ostomy equipment, yet complications continue to commonly occur.

A reliable and valid instrument to measure ostomy complications is needed for both researchers and clinicians in order to collect accurate and objective data. At the time of this study, there were no relevant instruments that could be used to measure both incidence and

severity of ostomy complications. Therefore, the purpose of this study was to evaluate the psychometric properties of a new instrument, the Ostomy Complication Severity Index (OCSI), designed to measure incidence and severity of ostomy complications that develop early in the postoperative period. We constructed an evidence-based conceptual model to guide the development of this new instrument and this study.

Specific research questions and hypotheses tested were:

1. Does the Pittman Ostomy Complication Severity Index (OCSI) demonstrate acceptable content validity, inter-rater reliability, and construct validity?

    Hypothesis 1a. The Ostomy Complication Severity Index will demonstrate acceptable content validity as evidenced by expert reviewer ratings of clarity, comprehensiveness, and appropriateness as well as content validity indices of at least 0.80.

    Hypothesis 1b. The OCSI will demonstrate acceptable inter-rater reliability with a Cohen's coefficient kappa greater than or equal to 0.60. [12]

    Hypothesis 1c. Construct validity will be supported by significant relationships among the following variables in the Pittman Ostomy Complication Conceptual Model: ostomy complication risk factors, individual ostomy complications, and total Ostomy Complication Severity Index scores.

    Hypothesis 1d. Construct validity will also be supported by significant relationships among the following variables in the conceptual model: Ostomy Complication Severity Index (OCSI) scores, Stoma Care Self-Efficacy scores, and Ostomy Adjustment scores.

2. What are the incidence and severity of ostomy complications 60 days post-operatively among adult patients who have had fecal ostomy surgery in a large Midwestern health system?

Conceptual Model

Development and psychometric testing of the OCSI were based on the Ostomy Complication Conceptual Model developed specifically for this study. As shown in Figure 1, the model illustrates the relationships among antecedents (intrinsic and extrinsic risk factors), mediator (stoma care self-efficacy), and outcomes (early ostomy complications and ostomy adjustment).

Methods

Development of the Ostomy Complication Severity Index (OCSI)

DeVellis' step-wise approach for developing instruments was rigorously followed to create the OCSI. The authors identified the construct to be measured, chose items that reflected the instrument's purpose, determined the format for measurement, and obtained expert review of the items.[13]

OCSI items were generated from an extensive review of research and clinical literature and from clinical expertise. The OCSI consisted of nine items from 0-3, with 0 meaning the complication was not present and 3 meaning it was extremely severe. The complications addressed by the items were, respectively, leakage, peristomal irritant dermatitis, pain, bleeding, stomal necrosis, stomal stenosis, retraction, mucocutaneous separation, and hyperplasia. The OCSI format includes Likert-like scale with individual item scores and a total score computed by summing the individual items. The minimum possible score is 0 and the maximum total score

possible is 27. Higher scores on the OCSI item or total score indicate more severe ostomy complication(s).

Study Procedures

Phase 1: To establish content validity of the instrument, an expert review was conducted as recommended by DeVellis and described further by Pittman and Bakas.[14] A panel of 10 Wound, Ostomy, Continence (WOC) nurse experts was recruited from across the United States to participate in a survey to establish the content validity of the instrument. Three experts were doctorally prepared, six were master's-prepared advanced practice nurses, and all were nationally recognized experts in the area of WOC nursing. Each content expert was mailed a packet of information that included the purpose of the survey, conceptual definitions of constructs being measured, and instructions for completing the survey. The content validity survey was developed based on recommendations of Wynd, Lynn, and Sacks.[12,15,16] Each expert was given specific instructions by which to evaluate the relevance of each of the nine individual items. In addition to item relevance, experts evaluated clarity, comprehensiveness, and appropriateness of each item. The item ratings were on a 4-point ordinal scale with the exception of comprehensiveness, which was on a 2-point nominal scale.

Phase II. A prospective longitudinal study design was implemented to examine the psychometric properties of the new measure. Following approval from university and hospital institutional review boards, a convenience sample of 71 adult patients who had undergone surgery to create a new fecal ostomy, either colostomy or ileostomy, was recruited from three hospital sites within a single healthcare system in the Midwest United States: a 750-bed Level I Trauma Center, a 350-bed university academic teaching hospital, and a 189-bed community hospital. Each of these acute care settings has one or more certified WOC nurses. Eligible

patients who were undergoing ostomy surgery were identified by a WOC nurse and/or physician in each facility. Potential subjects were informed of the opportunity to participate in the study while receiving standard inpatient care from a WOC nurse. To be eligible for this study, patients had to be: a) 18 years of age or older; b) undergoing surgery for creation of a fecal ostomy during their hospital stay; c) willing and able to return for a post-operative follow-up visit; and d) able to speak and read English. Patients were excluded from participation if they had any diagnosis indicating cognitive impairment or if they were unable to participate in the consent process.

Data Collection. Baseline data were collected prior to discharge (typically five to seven days post-operatively), and follow-up data were collected between 30 and 60 days post-operatively. Data were collected through self-administered surveys, medical review, and direct observation by trained, expert WOC nurses. Table 1 shows measures that were administered at each time point and data sources.

Measures

Demographic information and medical history were collected using a self- administered patient information survey. Stoma care self-efficacy was measured using the Stoma Care Self-Efficacy Scale, a well-established instrument developed by Bekkers and colleagues (13 items, Cronbach alpha= 0.94).[17] In our study, stoma care self-efficacy was measured at two points in time: baseline and follow-up. The patient or the caregiver, whichever person performed stoma care, completed the instrument. The Cronbach alpha for the scale was 0.96 in this study.

Ostomy adjustment was measured using the Ostomy Adjustment Inventory-23 (OAI-23), developed by Simmons and colleagues to measure social and psychological adjustment of patients with a fecal ostomy.[18] OAI-23 is a 23-item, multidimensional, self-report instrument

that consists of four subscales: acceptance, self-esteem, social engagement, and anger.[19] Evidence of validity was established in a large sample of 570 British participants with an ostomy. Cronbach alpha was 0.93 for the overall inventory. Test-retest reliability was found to be 0.83.[19] In our study, the OAI-23 was completed at follow-up and had a Cronbach alpha of 0.91.

Statistical Analyses

A primary aim of this study was to determine the psychometric properties of the OCSI. Content validity was examined by calculating the content validity index (CVI). The CVI, an objective method for quantitatively assessing content validity, is calculated based on expert ratings of item relevance, clarity, comprehensiveness, and appropriateness.[12] A CVI of 0.80 or higher is considered acceptable.[20] Individual item CVIs were computed by determining the number of items considered to be relevant (rated 3 or 4) by the experts divided by the total number of experts.[20] The total scale CVI is defined as the "proportion of items on an instrument that achieved a rating of 3 or 4 by all the content experts."[20] In this study, the total OCSI CVI was calculated by summing the individual CVI scores and dividing by the number of items.[16,20]

Inter-rater reliability was examined by having a second trained WOC nurse, in addition to the principal investigator (who is a certified WOC nurse), independently complete the instrument with a random sample of participants (n=6). Training included content of the instrument, use of the instrument, and applying the scoring rules. Cohen's coefficient kappa was computed to estimate inter-rater reliability.[21] In addition, the intra-class correlation coefficient was used to assess the strength of agreement between the raters for the OCSI total score using the metric defined by Landis and Koch (1977) in which 0-0.20 = slight agreement; 0.21-0.40 =

fair agreement; 0.41-0.60 = moderate agreement; 0.61-0.80 = substantial agreement; and 0.81-1.0 = almost perfect agreement.[22]

To assess construct validity of the OCSI, relationships among variables depicted in the Ostomy Complication Conceptual Model were examined. Specifically, relationships between ostomy risk factors (demographic, environmental, and clinical) and ostomy complications were examined. In addition, relationships among stoma care self-efficacy, ostomy adjustment, and ostomy complications were examined. Frequencies were used to examine all patient demographics. .Continuous variables were summarized using means and standard deviations and were compared using analysis of variance (ANOVA). Categorical variables were summarized using frequencies and percentages and were compared using chi-square tests. Correlations among variables were examined and multiple regression analysis was conducted to examine predictors of OCSI total scores. Analyses were performed using SPSS version 19 statistical software.

Results

A sample of 71 adult participants provided baseline data, and 58 participants were retained for follow-up. Thirteen (18%) were lost to follow-up: Two did not attend their follow-up appointments, two expired, and nine did not return repeated phone calls to schedule the follow-up visit.

The sample was predominantly white (96%) with nearly equal numbers of men (52%) and women (48%), and more than half (55%) were married or partnered. More than half had a college education (57%), 30% were employed, and 25% described their financial situation as insufficient to make ends meet. Approximately one third (34%) of participants required ostomy

surgery due to colorectal cancer, 21% to treat inflammatory bowel disease, and 44% as a result of trauma or other emergent conditions.[5]

Research Question 1: Does the Pittman Ostomy Complication Severity Index (OCSI) demonstrate acceptable content validity, inter-rater reliability and construct validity?

To test Hypothesis 1a (content validity), experts reviewed the OSCI and content validity was examined. As shown in Table 2, the mean rating for clarity was 3 or above (out of 4) for eight of the nine items. The average comprehensiveness rating was 1.8 (out of 2) or higher for all items. Eight of the nine items' mean rating for appropriateness was 3 (out of 4) or higher. One item (stomal bleeding) was rated lower on clarity (2.4) and appropriateness (2.5) by the experts and, therefore, was revised accordingly. Two types of CVI scores were calculated: 1) content validity of individual items and 2) content validity of the overall scale. All individual item CVI scores were acceptable, ranging from .88 to 1.0. The total OCSI CVI score was 0.91, supporting acceptable content validity of the overall instrument.[20] Detailed results are reported in Table 3. In summary, the results demonstrated acceptable content validity for the OCSI.

To test Hypothesis 1b (Inter-rater reliability), OCSI scoring was compared between two experts on a random sample of participants (n=6). As shown in Table 4, all individual items had a Cohen's coefficient kappa of 0.71 to 1.0. The total score of the OCSI had a Pearson's coefficient of 0.999 ($p \leq 0.001$) and an intra-class correlation coefficient of 0.991 ($p \leq 0.001$). The OCSI demonstrated acceptable inter-rater reliability on individual items and the total score[23].

To test Hypothesis 1c (construct validity), relationships among ostomy complications and demographic characteristics were examined (gender, education, employment, marital status, race, and comorbidities). Only female gender was associated with the most severe ostomy

complications ratings, specifically, for leakage (r= 0.324, p= 0.05), pain (r= 0.269, p= 0.05) and total OCSI scores (r= 0.320, p= 0.05). Women had significantly higher mean ostomy complication scores than men (p= 0.02).

Participants whose stoma site had not been marked pre-operatively by the WOC nurse had more severe retraction (r= 0.32, p= 0.01) and mucocutaneous separation (r= 0.30, p= 0.05). BMI was positively correlated with leakage (r=0.36, p= .01), retraction (r= 0.28, p= 0.05), mucocutaneous separation (r=0.26, p= .05), and ostomy complication total score (r= 0.32, p= 0.05). Participants with higher BMIs had more severe leakage, retraction, mucocutaneous separation, and higher ostomy complication severity scores.

Type of ostomy was correlated with leakage (r= 0.31, p= 0.05) and peristomal irritant dermatitis (r= 0.26, p= 0.05); participants with an ileostomy had higher severity scores on these two complications. Stoma/abdomen characteristics were significantly correlated with pain (r=0.30, p= 0.05), bleeding (r= 0.28, p=0.05), stomal necrosis (r=0.28, p= 0.05), retraction (r= 0.57, p= 0.01), mucocutaneous separation (r= 0.30, p= 0.05), and OCSI total score (r= 0.43, p= 0.01). Participants with flatter stomas and problematic skin folds/creases had more severe pain, bleeding, stoma necrosis, retraction, mucocutaneous separation, and higher overall ostomy complication scores.

To test construct validity of the OCSI further, relationships among individual risk factors and OCSI total scores using univariate and multivariate regression analyses were conducted (see Table 6). Univariate regression analysis identified two risk factors that were significantly associated with the development and severity of ostomy complications, stoma/abdomen characteristics ($p \leq 0.001$) and BMI ($p \leq 0.001$). When all risk factors were entered into the multivariate model, stoma/abdomen characteristics (p= 0.007) and BMI (p= 0.002) remained

independent predictors of total ostomy complication scores. These important results indicated that having flatter stomas and/or problematic skin folds at baseline predicted ostomy complication scores at follow-up and that higher BMI was related to higher ostomy complication scores at follow-up. Older age (p= 0.053) and needing more assistance with ADL functions (p= 0.057) at baseline approached significance as predictors of ostomy complications.

To test Hypothesis 1d (construct validity), relationships among Ostomy Complication Severity Index scores, Stoma Care Self-Efficacy scores, and Ostomy Adjustment Inventory-23 scores were examined. Stoma Care Self-Efficacy scores at follow-up were negatively associated with ostomy complication severity scores (r= -0.300, p=0.05). These findings indicate that patients with lower stoma care self-efficacy at follow-up. had higher incidence and severity of ostomy complications, meaning the less confident the participant was in their stoma care, the more ostomy complications that they had.

Stoma Care Self-Efficacy scores at baseline (r= 0.402, p= 0.002) and at follow-up (r= 0.599, ($p \leq 0.001$) were positively associated with Ostomy Adjustment scores. Participants who were more confident in caring for their stoma, both at baseline and at follow-up, had a higher ostomy adjustment score, indicating better adjustment.

A significant negative correlation of r= - 0.27 (p=0.04) was observed between total scores on the OCSI and the Ostomy Adjustment Inventory-23. These results indicate that participants who had a higher incidence of or more severe ostomy complications had more difficulty adjusting to having an ostomy.

In summary, strong evidence of construct validity for the Ostomy Complication Severity Index was identified. Relationships among ostomy complications, risk factors, stoma care self-efficacy, and ostomy adjustment were confirmed.

Research Question 2: What is the incidence and severity of ostomy complications post-operatively, among adult patients who have fecal ostomy surgery in a large Midwestern health system?

The incidence and severity of each ostomy complication are presented in Table 7. Results showed that 84% of participants had at least one ostomy complication after surgery. Almost 60% reported leakage of their pouching system at follow-up. Thirty-one (50%) participants reported having, or were observed to have, peristomal irritant dermatitis at follow-up. Twenty-six (42%) participants reported having stoma pain. At follow-up, 39 (62%) participants had a stoma that was above skin level versus 24 (39%) who had stomal retraction or a stoma that was at skin level or below. Eight (13%) participants had mucocutaneous separation.

Discussion

This study generated important new knowledge regarding the reliability and validity of a new instrument to measure incidence and severity of ostomy complications. The OSCI demonstrated acceptable content validity (CVI= 0.9). Expert ratings provided evidence of content validity by evaluating each item as clear, comprehensive, and appropriate. The OCSI demonstrated acceptable inter-rater reliability for each of the nine items (k= 0.71- 1.0) and excellent correlation of total OCSI scores between raters (r= 0.999, $p \leq 0.001$).

Theoretical relationships among ostomy complications, important individual risk factors, stoma care self-efficacy, and ostomy adjustment provided support for the construct validity of the OCSI. Gender, ostomy type, stoma/abdomen characteristics, BMI, and absence of stoma site marking by the WOC nurse were risk factors associated with the incidence and severity of ostomy complications in expected directions.

Three environmental factors examined as potential risk factors for complications were stoma site marking, pre-operative education, and post-operative education. Of these WOC nursing interventions, only the absence of stoma site marking was associated with greater severity of ostomy complications, specifically, stomal retraction (r= 0.32, p= 0.01) and mucocutaneous separation (r= 0.30, p= 0.05). These findings are consistent with prior studies reporting that patients who had their stoma site marked by the WOC nurse had fewer ostomy complications. [8,9,24,25] The Wound, Ostomy and Continence Nurses (WOCN) Society's best practice guidelines recommend stoma site marking pre-operatively to reduce the incidence of complications and improve self-care.[26] In addition, a joint position statement, developed and published by the American Society of Colorectal Surgeons and the WOCN Society (2007), recommended that all patients undergoing ostomy surgery have their stoma site marked by a colorectal surgeon or ostomy nurse.[27] The results of this study support these recommendations.

This study contributes valuable new information regarding the incidence and severity of fecal ostomy complications in the early post-operative period. Fifty-two (84%) participants had developed at least one ostomy complication at follow-up, consistent with other studies showing that ostomy complications are common.[4] Leakage was the most commonly occurring complication with almost 60% of the participants experiencing this problem. Peristomal irritant dermatitis was the next most commonly occurring complication with a rate of 50%, consistent with other studies reporting peristomal irritant dermatitis rates of 55%.[6]

An important and unique strength of this study was the measurement of both the incidence and severity of ostomy complications. This important information is not found elsewhere in the literature. For example, 11% of the participants in this study experienced leakage more than once a day and 20% had moderate to severe peristomal irritant dermatitis. In

practical terms, this means that 20% of the participants had not only a rash and irritation around their stoma, but also loss of epithelial tissue similar to a second degree burn. Almost 10% of study participants rated their stomal pain as 7 or greater. Thirty-nine percent had a stoma that was at skin level or below, which often leads to leakage and peristomal irritant dermatitis. The majority of those with stomal bleeding had superficial bleeding, but 2% had stomal bleeding that required medical intervention (sutures or transfusion). No other studies were found that reported ostomy complication severity in the detail provided by using the OCSI.

Two other instruments that measure physiological ostomy complications have recently been published; however, neither of them measures incidence and severity as does the OCSI. A study in Italy led to the development of an instrument designed to measure skin injury around the stoma but did not assess other stomal complications such as mucocutaneous separation, retraction, stomal stenosis, stomal necrosis, pain, or bleeding.[28] Kalashnikova et al.[29] recently reported a systematic method for diagnosing and selecting treatment options for ostomy complications. These investigators developed an algorithm to facilitate a uniform approach to diagnosing and treating ostomy complications. However, their algorithm has yet to be validated.[29]

Strengths and Limitations

A major strength of this study was the use of the Ostomy Complication Conceptual Model as a guiding framework for identifying specific risk factors, ostomy complications, self-efficacy, and ostomy adjustment. Application of conceptual models in ostomy research has been limited, and there are variations in study design, inconsistent definitions and terminology, and few measures with evidence of reliability and validity for data collection. As a result, comparing research findings across studies is difficult. The use of a conceptual model informs the design,

variables to be measured, and hypotheses to be tested. The conceptual model guides the choice of empirical indicators.[30] This development of an evidence-based conceptual model provided a structured and systematic approach for examining ostomy complications and the risk factors that may influence their development. Another major strength is that the use of this new instrument measures not only incidence but severity of the ostomy complication. No other instruments were identified that enable the measurement of both of these constructs.

Several limitations should be noted when interpreting the results of this study. One limitation was the small sample size used to examine inter-rater reliability. At the onset of the study, the goal was to collect inter-rater reliability data on one third of the participants. Unfortunately, due to unforeseen circumstances this was not feasible and inter-rater reliability was evaluated using data from six participants collected by two raters. Further reliability testing is recommended. A second limitation is that results may have limited generalizability and be applicable only to the early post-operative period and to patients in similar types of settings. Further testing of the OCSI is recommended to examine its utility for measuring ostomy complications that develop later in the post-operative period. In addition, the OCSI should be tested further with diverse patients across a variety of health care settings.

Conclusion

As the momentum for evidence-based practice accelerates, the need for standardized language and validated tools to measure outcomes of ostomy care becomes urgent.[31] This study's results support the reliability and validity of a new instrument to measure incidence and severity of ostomy complications. The OCSI can be used to identify not only the presence of ostomy complications, but also their severity. The instrument is brief, easy to use, and clinically practical, and it serves as an additional resource for nurse researchers and busy practitioners.

Ostomy complications negatively affect quality of life for individuals living with an ostomy, often resulting in physical and psychosocial limitations for these individuals and their families.[9] Not only do persons with an ostomy have to cope with a serious and often life-threatening diagnosis, but the placement of an ostomy requires significant changes to their lifestyle. This study contributes new scientific knowledge regarding incidence and severity of ostomy complications and relationships among risk factors, ostomy complications, stoma care self-efficacy, and ostomy adjustment. The findings provide a foundation upon which to build future research and develop interventions to improve care and enhance quality of life for individuals living with an ostomy.

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Figure 1: Pittman Ostomy Complication Conceptual Model

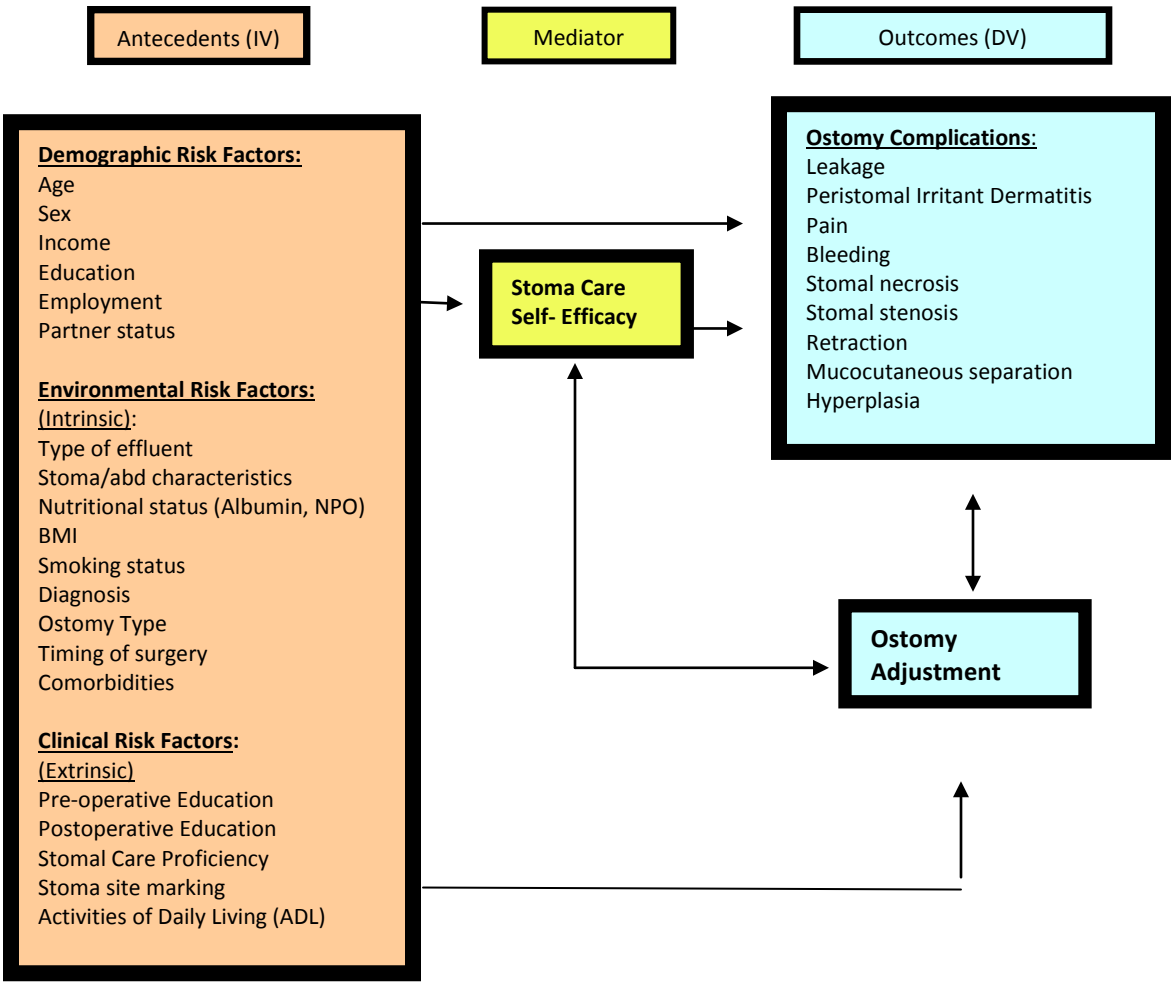

Table 1: Data Collection Timeline and Sources:

Variables	Baseline	Follow-Up	Data Source
Patient survey (age, gender, education, occupation, income, smoking, comorbidities, ostomy education provided by WOC nurse, ADL status)	X		Self-report
Ostomy Complication Severity Index (leakage, peristomal irritant dermatitis, pain, bleeding, stomal necrosis, stomal stenosis, retraction, mucocutaneous separation, hyperplasia)		X	WOC nurse observation Self-report
Ostomy risk factors (diagnosis, timing of surgery, ostomy type, type of effluent, stoma/abd characterisitics, stoma-care proficiency, stoma site marking, NPO status, BMI)	X		Medical record review Self report WOC nurse observation
Stoma Care Self-Efficacy Scale	X	X	Self report
Ostomy Adjustment Inventory-23		X	Self report

Table 2: Ostomy Complication Severity Index: Panel of Experts Mean Ratings

OCSI	**Mean (SD)**			
	Relevance of item **1. Item is NOT relevant** **2. Item needs MAJOR revision to be relevant** **3. Item needs MINOR revision to be relevant** **4. Item IS relevant**	**Clarity of item** **1. Item is NOT clear** **2. Item needs MAJOR revision to be clear** **3. Item needs MINOR revision to be clear.** **4. Item IS clear**	**Comprehensiveness of item** **1. Item should be deleted.** **2. Item should be retained.**	**Appropriateness of numeric rating scale for each item** **1. Rating scale is NOT appropriate.** **2. Rating scale needs MAJOR revision to be appropriate.** **3. Rating scale needs MINOR revision to be appropriate.** **4. Rating scale is appropriate.**
Leakage	3.6 (0.97)	3.2 (1.23)	1.9 (0.32)	3.4 (0.97)
Peristomal irritant dermatitis	4.0 (0)	3.9 (0.33)	2.0 (0)	3.3 (0.95)
Pain	3.3 (0.95)	3.0 (1.15)	1.9 (0.32)	3.2 (1.03)
Bleeding	3.0 (1.15)	2.4 (1.13)	1.8 (0.42)	2.5 (1.01)
Stomal necrosis	3.8 (0.63)	3.9 (0.33)	2.0 (0)	3.5 (0.71)
Stomal stenosis	3.8 (0.63)	3.3 (1.00)	1.9 (0.32)	3.0 (1.12)
Retraction	3.8 (0.63)	3.4 (1.13)	1.9 (0.32)	3.7 (0.71)
Mucocutaneous separation	3.8 (0.63)	3.6 (0.73)	2.0 (0)	3.4 (0.97)
Hyperplasia	3.6 (0.97)	3.8 (0.67)	2.0 (0)	3.7 (0.67)
Total (mean)	3.6	3.4	1.9	3.3

Table 3: Ostomy Complication Severity Index: Item and Total CVI Scores

	Rated:		
OCSI	**1 or 2**	**3 or 4**	**Item CVI**
Leakage	1	9	.90
Peristomal irritation	0	10	1.00
Pain	1	9	.90
Bleeding	2	8	.88
Stoma necrosis	1	9	.90
Stoma stenosis	1	9	.90
Retraction	1	9	.90
Mucocutaneous separation	1	9	.90
Hypergranulation	1	9	.90
Total CVI			.91

Table 4: Ostomy Complication Severity Index: Inter-rater reliability analysis (n=6)

OCSI Item	**% Agreement**	**Kappa**
Leakage	100%	1.0
Peristomal irritant dermatitis	100%	1.0
Pain	75%	0.7
Bleeding	100%	1.0
Stomal necrosis	100%	1.0
Stomal stenosis	100%	1.0
Retraction	100%	1.0
Mucocutaneous separation	100%	1.0
Hyperplasia	100%	1.0
Total OCSI score Pearson's Correlation Intra-class Correlation		*(p)* 0.999 (≤0.001) 0.991 (≤0.001)

Table 5: Correlations among risk factors and ostomy complications (OCSI items)

Variables	Leakage	Peri-stomal dermatitis	Pain	Bleed-ing	Stomal Necrosis	Stomal Stenosis	Retrac-tion	MC Sep	Hyper Plasia	Total score
Gender	**.32***	.198	**.27***	.25	.14	.09	.11	.03	-.21	**.32***
Age	-.15	-.08	-.01	.03	-.15	-.03	-.01	.04	.20	-.06
Diagnosis	.05	-.05	-.09	-.03	-.01	.17	-.09	.02	.07	-.03
Timing of surgery	-.16	-.18	-.12	.04	-.10	.02	.14	.13	.15	-.07
Ostomy Type	**.31***	**.26***	.20	-.07	.11	-.01	-.16	.06	-.09	.19
Type of Effluent	-.03	.03	-.05	-.08	.12	.05	-.08	-.12	.07	-.06
Stoma/abd characteristics	.22	.11	**.30***	**.28***	**.28***	.05	**.57****	**.30***	-.10	**.43****
Stoma care proficiency	.02	-.15	.01	.05	.20	-.03	.09	.14	.04	.03
ADL function	-.07	-.20	**-.32***	**-.25***	.17	**.29***	-.11	-.14	.08	-.23
Pre-operative education by WOC nurse	-.13	-.12	-.13	.01	-.17	-.10	.10	.15	.02	-.05
Stoma site marked by WOC nurse	-.02	-.12	-.02	.03	-.13	.13	**.32****	**.30***	.07	.11
NPO status	-.21	-.22	-.11	**-.35****	-.08	-.04	-.02	-.08	.10	**-.25***
BMI (Spearman *r)*	**.42****	**.29****	.20	.22	.17	.05	.25	.22	.13	**.36****
BMI2 (continuous)	**.36****	.11	.13	.17	.14	.03	**.28***	**.26***	-.10	**.32***
Smoking status	-.04	.03	-.01	-.12	-.11	-.09	-.22	-.01	.18	-.09
Post-operative education by WOC nurse	-.11	-.09	-.13	-.03	.15	-.12	-.05	-.14	-.06	-.14

Table 6: Univariate and Multivariate regression analyses of risk factors and ostomy complications (OCSI)

Outcome	**Covariate**	**Univariate**				**Multivariate**			
		B	**SE**	**Beta**	***p***	**B**	**SE**	**Beta**	***p***
OCSI Total score	Age	-.177	.404	-.057	.663	.948	.476	.302	**.053**
	Diagnosis	-.107	.490	-.028	.828	1.202	.644	.320	.068
	Timing of surgery	-.160	.319	-.065	.619	-.856	.528	-.348	.112
	Ostomy type	.487	.331	.188	.147	-.007	.395	-.003	.985
	Type of effluent	-.341	.811	-.055	.676	.997	.855	.159	.250
	Stoma/abd characteristics	**1.503**	**.407**	**.433**	**.000**	**1.269**	**.445**	**.365**	**.007**
	Stoma care proficiency	.119	.479	.032	.805	-.256	.507	-.070	.616
	ADL	-.796	.439	-.230	.075	-.819	.420	-.236	**.057**
	Pre-operative education by WOC	-.136	.329	-.054	.681	-.196	.377	-.078	.605
	Stoma site marked by WOC	.256	.306	.109	.408	.566	.375	.241	.138
	NPO status	-.882	.449	-.248	**.054**	-.496	.532	-.139	.356
	BMI	**1.375**	**.370**	**.435**	**.000**	**1.412**	**.427**	**.441**	**.002**
	Smoking	-.322	.447	-.093	.474	.122	.403	.035	.764
	Post-operative education by WOC	-.527	.480	-.143	.277	-.376	.525	-.102	.478

Table 7: Incidence and severity of ostomy complications at 30-60 days by study site

Ostomy Complications	**SITE 1**	**SITE 2**	**SITE 3**	**TOTAL**		
	n= 18 n (%)	n= 42 n (%)	n= 10 n (%)	n= 70 n (%)	*Chi square*	*p*
Leakage						
None	5 (36)	13 (35)	7 (64)	25 (40)	7.52	.276
1-2x/mo	3 (21)	9 (24)	1 (9)	13 (21)		
1-2x/wk	6 (43)	10 (27)	1 (9)	17 (27)		
1-2x/day	0	5 (14)	2 (18)	7 (11)		
Peristomal Irritant Dermatitis						
None	9 (64)	15 (41)	7 (64)	31 (50)	6.15	.407
Mild	2 (14)	12 (32)	3 (27)	17 (27)		
Moderate	3 (21)	6 (16)	1 (9)	10 (16)		
Severe	0	4 (11)	0	4 (7)		
Stomal Pain						
None	7 (50)	21 (57)	8 (73)	36 (58)	4.48	.612
1-3	3 (21)	8 (22)	3 (27)	14 (23)		
4-6	1 (7)	4 (11)	0	5 (8)		
7-10	3 (21)	4 (11)	0	7 (11)		
Mean (SD)	1.25 (2.5)	1.89 (2.9)	1.64 (2.7)	1.71 (2.8)		.794
Stomal Bleeding						
None	8 (57)	25 (68)	9 (82)	42 (68)	8.71	.191
Superficial	4 (29)	12 (32)	1 (9)	17 (27)		
Moderate	1 (7)	0	1 (9)	2 (3)		
Severe	1 (7)	0	0	1 (2)		
Stomal Necrosis						
None	15 (100)	36 (97)	11 (100)	62 (98)	0.71	.700
Stoma Dusky	0	1 (3)	0	1 (2)		
Stoma 50% black	0	0	0			
Stoma >50% black	0	0	0			
Stomal Stenosis						
None	14 (93)	36 (97)	10 (91)	60 (95)	3.71	.447

<5th digit diameter, no discomfort	0	1 (3)	0	1 (2)		
<5th digit diameter, occasional discomfort	1 (7)	0	1 (9)	2 (3)		
Unable to insert 5th digit, no output	0	0	0	0		
Stomal Retraction						
Stoma above skin	6 (40)	27 (73)	6 (55)	39 (62)	12.48	.052
Stoma skin level	6 (40)	9 (24)	2 (18)	17 (27)		
Stoma below skin level	3 (20)	1 (3)	2 (18)	6 (10)		
Stoma >2cm below skin level	0	0	1 (9)	1 (2)		
Mucocutaneous Separation						
None	11 (73)	35 (95)	9 (82)	55 (87)	10.17	.118
1-49%	2 (13)	1 (3)	0	3 (5)		
50-74%	1 (7)	0	0	1 (2)		
75-100%	1 (7)	1 (3)	2 (18)	4 (6)		
Hyperplasia						
None	13 (87)	36 (97)	11 (100)	60 (95)	3.33	.190
1-49%	2 (13)	1 (3)	0	3 (5)		
50-74%	0	0	0	0		
75-100%	0	0		0		
Ostomy Complications present						
No	1 (7)	6 (16)	3 (30)	10 (16)		
Yes	13 (93)	31 (84)	8 (73)	52 (84)	1.85	.397
OCSI Total Score	5 (3.5)	4 (3.5)	3 (3.8)	4 (3.5)		.546